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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/358,755	07/22/99	KAWABATA H	

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MURPHY, EXAMINER

ART UNIT	PAPER NUMBER
1034	9

04/20/00

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/358,755

Applicant(s)

KAWABATA ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 12-18 and 20-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) _____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 17) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☒ Other: *Sequence Comparison A*.

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DETAILED ACTION

Election/Restrictions

Claims 1-23 were originally filed.

Applicant's election of Group I, claims 1-11 and 19 in Paper No. 7, 4/5/2000 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 12-18 and 20-23 are withdrawn from further consideration by the examiner as being drawn to a non-elected invention 37 CFR 1.142(b).

Claims 1-11 and 19 are under consideration.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Nucleic Acid Encoding Transferrin Receptor-like Proteins.

Claim Rejections - 35 USC § 112 first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding SEQ ID NO: 1, does not reasonably provide enablement for any other nucleic acid. There is not adequate guidance as to the nature of the nucleic acid which Applicants claim. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with this claim.

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Claims 1, 8 and 19 are overly broad in the recitation of "TfR2". since no guidance as to what constitutes "TfR2" polypeptide is provided within the claims. The broad scope of claims 1, 8 and 19 can be read to encompass any isolated nucleic acid encoding a polypeptide. There is no guidance provided in the specification as to how one of ordinary skill in the art would generate a nucleic acid encoding a polypeptide other than those exemplified in the specification. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. Given the breadth of claims 1, 8 and 19 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention. Claims 2-7 and 9-11 are rejected insofar as they depend on the recitation of "TfR2" in claims 1, 8 and 19.

Claim 11 recites the term "capable of ...". The specification is non-enabling for oligonucleotides that do not bind and inhibit translation of the mRNA of claim 9, and are only capable of, if further modified such that they can bind, because Applicant has not taught how to further modify oligonucleotides such that they can bind and inhibit translation of the mRNA of claim 9. It has been held that an element is "capable of" performing a function is not a positive limitation but only requires the ability to perform. It does not constitute a limitation in any patentable sense. In re Hutchinson, 69 USPQ 138.

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Claim Rejections - 35 USC § 112 second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 8 and 19 are indefinite in that they only describe the peptide of interest by an arbitrary protein name. There is nothing in the claims which distinctly claims the protein and variants thereof. For example, others in the field may isolate the same protein and give said protein an entirely different name. Applicant should particularly point out and distinctly claim the polynucleotide encoding the TfR2 polypeptide by claiming structural characteristics associated with the protein (e.g. nucleic acid, molecular weight, etc.). Claiming biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly claim what that protein is.

Claim 5 is vague and indefinite in the recitation of the term "substantially", which is a conditional term and renders the claim indefinite. The metes and bounds of the claim thus cannot be ascertained. This rejection could be obviated by supplying specific conditions supported by the specification which Applicant considers to be "substantial".

Claim 8 is vague and indefinite in the recitation of the term "functional", which is a conditional term and renders the claim indefinite. The metes and bounds of the claim thus cannot be ascertained. This rejection could be obviated by supplying specific conditions supported by the specification which Applicant considers to be "functional".

Claim 11 recites the term "specifically binding", which is a conditional term and renders the claim indefinite. Furthermore, some nucleic acids which might bind under conditions of moderate stringency, for example, would fail to bind under conditions of high stringency. The metes and bounds of the claim thus cannot be ascertained. This rejection could be obviated by

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supplying specific conditions supported by the specification which Applicant considers to be "specific".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al. (1996).

Hillier et al. discloses the cloning of an EST which would hybridize to the mRNA of claim 9, and inhibit translation. See Sequence Comparison A, attached.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al (1996) in view of Chonn et al. (1995).

The disclosure of Hillier et al. has been set forth above. The disclosure of Hillier et al. differs from the disclosed invention by not disclosing a composition of the antisense oligonucleotide in a hydrophobic carrier. Chonn et al. teaches the use of liposomes to deliver

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antisense oligonucleotides (page 703, column 1, second paragraph). Therefore, it would have been obvious to one of skill in the art at the time the invention was made to use the liposomes of Chonn et al to deliver the antisense oligonucleotide of Hillier et al. The motivation is provided in Hillier et al. which teaches that liposomes are able to resolve the problems of extracellular degradation by nucleases and poor membrane permeability that are inherent for oligonucleotide drugs.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703-308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Joseph F. Murphy, Ph. D.
Patent Examiner
Art Unit 1644
April 18, 2000

Prema Mertz
PREMA MERTZ
PRIMARY EXAMINER